UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF NEW YORK

TIMOTHY J. RIZZO,

Plaintiff

v.

APPLIED MATERIALS, INC., and GLOBALFOUNDRIES U.S., INC.

Defendants.

6:15-CV-00557 (MAD) (ATB)

DEFENDANTS' STATEMENT OF MATERIAL FACTS IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

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Pursuant to Fed. R. Civ. P. 56 and L.R. 7.1(a)(3), Defendants GlobalFoundries U.S., Inc. ("GlobalFoundries") and Applied Materials, Inc. ("Applied Materials") (collectively, "Defendants") respectfully submit this Statement of Material Facts in support of their Motion for Summary Judgment.

I. PLAINTIFF'S ALLEGED MEDICAL CONDITION

1. Plaintiff Timothy Rizzo alleges that he suffers from a rare autoimmune disease called granulomatosis with polyangiitis ("GPA") (formerly known as Wegener's Disease) as a result of exposure to chemicals at GlobalFoundries' semiconductor-manufacturing facility ("Fab 8"). (ECF No. 35, Am. Compl. ¶¶ 2, 67.)

II. GPA HAS NO KNOWN CAUSE

- 2. The general medical and scientific consensus is that the cause of GPA is unknown. (Hoffman Decl. ¶ 5; Garabrant Decl. ¶ 9; Reisman Decl. ¹ Ex. 1, Miloslavsky Dep. at 129:11-19; Reisman Decl. Ex. 5, Hodgman Dep. at 149:15-23.)
- 3. No article, study or text has reported a causal relationship between any occupational or environmental exposure and GPA. (Garabrant Decl. ¶ 12; Reisman Decl. Ex. 1, Miloslavsky at Dep. at 130:16-23 (as to silica, the only exposure about which Dr. Miloslavsky provided a causation opinion); Reisman Decl. Ex. 7, Wang Dep. at 188:14-189:4; 253:2-11; 430:8-431:16.)
- 4. The American College of Rheumatology ("ACR") is an authoritative and respected professional organization of physicians and scientists that address the diagnosis,

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¹ All references to the "Reisman Decl." refer to the Declaration of Sharyl A. Reisman, in Support of Defendants' Motion for Summary Judgment, dated December 21, 2016, filed simultaneously herewith.

treatments, causes of rheumatologic diseases. (Reisman Decl. Ex. 1, Miloslavsky Dep. at 44:20-45:2; Reisman Decl. Ex. 5, Hodgman Dep. at 74:4-12.)

5. The ACR article entitled "Granulomatosis with Polyangiitis (Wegener's)" states that "[t]he cause of GPA is unknown." (Reisman Decl. Ex. 5, Hodgman Dep. at 74:13-25.)

III. GPA IS NOT ASSOCIATED WITH EXPOSURE CONDITIONS SIMILAR TO THOSE ALLEGED BY PLAINTIFF

- 6. No article, study or text has found any association between GPA and environmental or chemical exposures lasting less than six months. (Reisman Decl. Ex. 1, Miloslavsky Dep. at 122:16-123:2; Reisman Decl. Ex. 5, Hodgman Dep. at 96:8-19 (as to crystalline silica, the only chemical for which Dr. Hodgman noted even a suggestion of an association with respect to autoimmune disorders with vasculitis); Reisman Decl. Ex. 7, Wang Dep. at 185:10-15 (as to silica); 188:9-13 (as to silica); 346:6-9; 427:23-428:18.)
- 7. No article, study or text has reported an association between GPA and exposures in the semiconductor or electronics industry. (Garabrant Decl. ¶ 13; Reisman Decl. Ex. 5, Hodgman Dep. at 46:7-10; Reisman Decl. Ex. 1, Miloslavsky Dep. at 121:23-122:8; *see also* Reisman Decl. Ex. 7, Wang Dep. at 342:24-343:9; 348:7-15; 427:12-22.)
- 8. No article, study or text has reported an association between GPA and any exposure with less than a multi-year latency period. (Garabrant Decl. ¶ 30; Reisman Decl. Ex. 7, Wang Dep. at 185:16-20 (as to silica), 429:17-430:6; Reisman Decl. Ex. 1, Miloslavsky Dep. at 144:5-145:2.)

IV. DR. MILOSLAVSKY'S OPINION IS UNRELIABLE

9. A comprehensive literature review is a prerequisite to any reliable causation opinion. (Garabrant Decl. ¶ 22; Reisman Decl. Ex. 5, Hodgman Dep. at 49:18-50:9.)

- 10. In determining causation, it is not appropriate only to look at studies that support a causal hypothesis. (Reisman Decl. Ex. 5, Hodgman Dep. at 49:25-50:9.)
- 11. Plaintiff's rheumatologist, Dr. Eli Miloslavsky, did not "attempt to undertake a comprehensive review and analysis of all the literature that exists on exposures to silica and GPA." (Reisman Decl. Ex. 1, Miloslavsky Dep. at 127:15-23; *see also* Hoffman Decl. ¶ 44; Garabrant Decl. ¶ 73.)
- 12. In forming his opinions in this case, Dr. Miloslavsky reviewed and relied upon only those studies that he believed supported his position that exposure to crystalline silica causes GPA. (Reisman Decl. Ex. 1, Miloslavsky Dep. at 126:25-128:7.)
- 13. Dr. Miloslavsky's opinion that exposure to crystalline silica causes GPA is inconsistent with the scientific consensus that the cause of GPA is unknown. (Hoffman Decl. ¶ 5; Garabrant Decl. ¶ 9; Reisman Decl. Ex. 1, Miloslavsky Dep. at 129:4-19; Reisman Decl. Ex. 5, Hodgman Dep. at 149:15-23.)
- 14. Dr. Miloslavsky is not aware of any text, authoritative body or professional organization that has published the opinion that exposure to crystalline silica causes GPA. (Reisman Decl. Ex. 1, Miloslavsky Dep. at 130:16-23.)

V. THE ARTICLES DR. MILOSLAVSKY RELIES UPON DO NOT SUPPORT CAUSATION

- 15. Dr. Miloslavsky relies on six articles to support his opinion that exposure to crystalline silica causes GPA:
 - Gomez-Puerta, J.A., 2013. The association between silica exposure and development of ANCA-associated vasculitis: systematic review and metaanalysis. Autoimmun. Rev. 12, 1129-1135 ("Gomez-Puerta 2013");

- Hogan, S.L., 2001. Silica exposure in anti-neutrophil cytoplasmic autoantibody-associated glomerulonephritis and lupus nephritis. J. Am. Soc. Nephrol. 12, 134-142 ("Hogan 2001");
- Hogan, S.L., 2007. Association of silica exposure with anti-neutrophil
 cytoplasmic autoantibody small-vessel vasculitis: a population-based, casecontrol study. Clin. J. Am. Soc. Nephrol. 2, 290-299 ("Hogan 2007");
- Nuyts, G.D., 1995. Wegener granulomatosis is associated to exposure to silicon compounds: a case-control study. Nephrol. Dial. Transplant. 10, 1162-1165 ("Nuyts 1995");
- Lane, S.E., 2003. Are environmental factors important in primary systemic vasculitis? A case-control study. Arthritis & Rheumatism 48, 814-823 ("Lane 2003"); and
- Webber, M.P., 2015. Nested case-control study of selected systemic autoimmune diseases in World Trade Center rescue/recovery workers.
 Arthritis Rheumatol. 67, 1369-1376 ("Webber 2015").

(Reisman Decl. Ex. 1, Miloslavsky Dep. at 126:25-127:11.)

16. None of the studies that Dr. Miloslavsky relies on addresses exposure in the semiconductor industry. (Reisman Decl. Ex. 1, Miloslavsky Dep. at 121:23-122:8.)

A. GOMEZ-PUERTA 2013

17. Gomez-Puerta 2013 is a meta-analysis (*i.e.*, an analysis of other epidemiologic studies) that examined potential associations between silica exposure and ANCA-associated vasculitis. (Hoffman Decl. ¶¶ 29a-29c; Garabrant Decl. ¶ 40; Reisman Decl. Ex. 1, Miloslavsky Dep. at 139:12-22.)

- 18. ANCA-associated vasculitis is a category of diseases that includes a number of individual diseases with differing diagnoses, presentations, treatments and causes. (Hoffman Decl ¶ 12; Garabrant Decl. ¶ 16; Reisman Decl. Ex. 1, Miloslavsky Dep. at 55:19-56:18.)
- 19. Gomez-Puerta 2013 does not draw any conclusion regarding an association between silica exposure and GPA. (Hoffman Decl ¶ 29j; Garabrant Decl. ¶ 40; Reisman Decl. Ex. 1, Miloslavsky Dep. at 142:6-12.)
- 20. Studies failing to differentiate between GPA and other ANCA-associated vasculitis cannot establish causation as to GPA. (Hoffman Decl ¶ 16; Garabrant Decl. ¶ 16; Reisman Decl. Ex. 1, Miloslavsky Dep. at 57:17-58:3; Reisman Decl. Ex. 5, Hodgman Dep. at 104:10-24.)
- 21. The studies examined in Gomez-Puerta 2013 involved mean latency periods well in excess of ten years. (Hoffman Decl ¶ 29e; Garabrant Decl. ¶ 40; Reisman Decl. Ex. 1, Miloslavsky Dep. at 143:15-145:2; Reisman Decl. Ex. 7, Wang Dep. at 207:11-21.)
- 22. In the studies that were examined in Gomez-Puerta 2013, the average duration of exposure was 21 years. (Hoffman Decl ¶ 29f; Garabrant Decl. ¶ 40; Reisman Decl. Ex. 1, Miloslavsky Dep. at 145:10-16; Reisman Decl. Ex. 7, Wang Dep. at 206:24-207:10.)
- 23. Dr. Miloslavsky agrees with the conclusion reached in Gomez-Puerta 2013 that "[o]ur summary estimates *lend support to the hypothesis* that silica *may act* as an environmental 'trigger' for the development of [ANCA-associated vasculitis] However, further studies are warranted" (emphasis added) (Reisman Decl. Ex. 1, Miloslavsky Dep. at 147:3-148:24.)

B. **HOGAN 2001**

- 24. Hogan 2001 examined potential associations between silica exposure and ANCA-associated vasculitis and reported subanalyses for GPA. (Hoffman Decl. ¶ 30a; Garabrant ¶ 35; Reisman Decl. Ex. 1, Miloslavsky Dep. at 149:16-150:14.)
- 25. The odds ratio a measure of association between an exposure and an outcome for GPA in Hogan 2001 was not statistically significant. (Hoffman Decl. ¶ 30g; *see also* Garabrant Decl. ¶ 35; Reisman Decl. Ex. 1, Miloslavsky Dep. at 151:11-19; Reisman Decl. Ex. 5, Hodgman Dep. at 153:4-15.)
- 26. Hogan 2001 cannot prove or disprove an association between silica exposure and GPA. (Reisman Decl. Ex. 1, Miloslavsky Dep. at 151:24-152:21; Reisman Decl. Ex. 5, Hodgman Dep. at 156:24-157:8.)
- 27. Hogan 2001 only considered subjects exposed if they reported regular exposure to silica for at least one to two years. (Hoffman Decl. ¶ 30d; Garabrant ¶ 35; Reisman Decl. Ex. 1, Miloslavsky Dep. at 153:13-17; Reisman Decl. Ex. 5, Hodgman Dep. at 157:9-25.)
- 28. Mr. Rizzo would have been considered unexposed in the Hogan 2001 study. (Garabrant ¶ 35; Reisman Decl. Ex. 1, Miloslavsky Dep. at 153:18-20.)

C. HOGAN 2007

- 29. Hogan 2007 examined potential associations between chronic silica exposure and ANCA-associated vasculitis. (Reisman Decl. Ex. 1, Miloslavsky Dep. at 155:25-156:25.)
- 30. Hogan 2007 does not make any findings specific to GPA. (Hoffman Decl. ¶ 23b; Garabrant Decl. ¶ 48; Reisman Decl. Ex. 1, Miloslavsky Dep. at 156:21-157:5; Reisman Decl. Ex. 7, Wang Dep. at 227:6-9.)

- 31. Hogan 2007 only considered subjects exposed if they had held jobs involving silica exposure for at least one year. (Hoffman Decl. ¶ 23a; Garabrant Decl. ¶ 48; Reisman Decl. Ex. 1, Miloslavsky Dep. at 157:16-21; Reisman Decl. Ex. 7, Wang Dep. at 241:4-7, 241:20-24.)
- 32. Mr. Rizzo would have been considered unexposed in the Hogan 2007 study. (Garabrant Decl. ¶ 48; Reisman Decl. Ex. 1, Miloslavsky Dep. at 157:22-158:2; Reisman Decl. Ex. 7, Wang Dep. at 241:15-24.)
- 33. The median duration of exposure of subjects in Hogan 2007 was 13 years. (Hoffman Decl. ¶ 23b; Garabrant Decl. ¶ 48; Reisman Decl. Ex. 1, Miloslavsky Dep. at 158:10-16.)
- 34. Hogan 2007 found no increased risk of ANCA-associated vasculitis among subjects with low or medium exposure to silica. (Hoffman Decl. ¶ 23b; Garabrant Decl. ¶ 48; Reisman Decl. Ex. 1, Miloslavsky Dep. at 158:17-21; Reisman Decl. Ex. 7, Wang Dep. at 242:5-15.)
- 35. Mr. Rizzo would have been in the "lack of increased risk" category in the Hogan 2007 study. (Garabrant Decl. ¶ 48; Reisman Decl. Ex. 1, Miloslavsky Dep. at 159:3-7.)

D. <u>NUYTS 1995</u>

- 36. Nuyts 1995 examined potential associations between silica exposure and GPA. (Hoffman Decl. ¶ 40a; Garabrant Decl. ¶ 33; Reisman Decl. Ex. 1, Miloslavsky Dep. at 160:5-18.)
- 37. The occupations studied in Nuyts 1995 involve very high exposure to crystalline silica dust, including bricklaying, sandblasting, construction, and farming where workers are exposed to grain dusts. (Hoffman Decl. ¶ 40d; Garabrant Decl. ¶ 33; Reisman Decl. Ex. 1,

Miloslavsky Dep. at 162:10-24; Reisman Decl. Ex. 5, Hodgman Dep. at 168:25-169:7; Reisman Decl. Ex. 7, Wang Dep. at 348:7-15.)

38. The occupations studied in Nuyts 1995 involve far higher silica dust exposures than Mr. Rizzo's alleged exposure and do not fit Mr. Rizzo's case. (Garabrant Decl. ¶ 33; *see also* Reisman Decl. Ex. 5, Hodgman Dep. at 168:25-169:12; Reisman Decl. Ex. 7, Wang Dep. at 348:7-15, 362:21-363:13.)

E. LANE 2003

- 39. Lane 2003 examined potential associations between silica exposure and GPA. (Hoffman Decl. ¶¶ 24a-24b; Garabrant Decl. ¶ 36; Reisman Decl. Ex. 1, Miloslavsky Dep. at 165:22-166:10, 180:10-14.)
- 40. Lane 2003 found no statistically significant increased risk for GPA, even in the high exposure group. (Hoffman Decl. ¶ 24b; Garabrant Decl. ¶ 36; Reisman Decl. Ex. 1, Miloslavsky Dep. at 180:17-181:7; Reisman Decl. Ex. 5, Hodgman Dep. at 158:25-160:8; Reisman Decl. Ex. 7, Wang Dep. at 227:24-228:7.)
- 41. Lane 2003's findings for primary systematic vasculitis (which includes more diseases than ANCA-associated vasculitis) were based on an average duration of exposure of over 20 years. (Hoffman Decl. ¶ 24b; Reisman Decl. Ex. 1, Miloslavsky Dep. at 181:8-18; Reisman Decl. Ex. 7, Wang Dep. at 228:17-23.)

F. **WEBBER 2015**

42. Webber 2015 examined potential associations between autoimmune diseases and acute exposures to a mixture of metals, solvents and dusts at the World Trade Center site.

(Hoffman Decl. ¶¶ 26a-26b; Reisman Decl. Ex. 1, Miloslavsky Dep. at 185:10-186:7, 186:23-187:12.)

- 43. Webber 2015 included only one case of GPA. (Hoffman Decl. ¶¶ 26a-26b; Reisman Decl. Ex. 1, Miloslavsky Dep. at 186:8-16.)
- 44. Webber 2015 is not specific to silica. (Hoffman Decl. ¶ 26b; Reisman Decl. Ex. 1, Miloslavsky Dep. at 186:23-187:12.)
- 45. Webber 2015 does not draw any conclusion linking exposures at the World Trade Center site with GPA. (Reisman Decl. Ex. 1, Miloslavsky Dep. at 186:17-22.)
- 46. Webber 2015 is not sufficient to reach a conclusion linking exposures at the World Trade Center site with GPA. (Hoffman Decl. ¶ 26b; Reisman Decl. Ex. 1, Miloslavsky Dep. at 186:17-188:20.)

VI. DR. WANG IS UNQUALIFIED AND HIS OPINION IS UNRELIABLE

- 47. Dr. Robert S. Wang was Mr. Rizzo's treating pulmonologist from January 31 to December 2013. (Reisman Decl. Ex. 7, Wang Dep. at 172:21-173:11.)
- 48. Dr. Wang's "specialty is in pulmonology and not rheumatology, toxicology or occupational medicine[.]" (Reisman Decl. Ex. 7, Wang Dep. at 176:16-19.)
- 49. Dr. Wang is not an expert in epidemiology, toxicology, occupational medicine, industrial hygiene, rheumatology or GPA. (Reisman Decl. Ex. 7, Wang Dep. at 78:16-79:12, 83:11-14.)
- 50. Dr. Wang "wouldn't be able to provide expert opinions to the Office of Professional Medical Conduct on rheumatology, or toxicology, or otolaryngology, or epidemiology." (Reisman Decl. Ex. 7, Wang Dep. at 269:14-270:8.)
- 51. Prior to this case, Dr. Wang had given testimony that an occupational exposure caused a medical condition only twice: once involving chronic obstructive pulmonary disease

and once involving occupational asthma. (Reisman Decl. Ex. 7, Wang Dep. at 25:5-9, 9:8-14, 30:8-11.)

- 52. In Dr. Wang's entire career he has seen only two patients with GPA (including Mr. Rizzo) and treated only the pulmonary symptoms of the disease. (Reisman Decl. Ex. 7, Wang Dep. at 87:24-88:6, 94:16-95:3, 392:4-6.)
- 53. Dr. Wang has never diagnosed a patient with GPA, and no patient has ever come to him for the treatment of GPA. (Reisman Decl. Ex. 7, Wang Dep. at 88:25-89:6.)
- 54. This case is the "first and only time that [Dr. Wang] has told a patient that their Wegener's disease [(GPA)] was due to some occupational exposure[.]" (Reisman Decl. Ex. 7, Wang Dep. at 95:4-20.)
- 55. Dr. Wang testified during Mr. Rizzo's workers' compensation proceeding that he would "defer to the opinion of a rheumatologist with respect to an opinion connecting workplace exposure to Mr. Rizzo's development of Wegener's [(GPA)][.]" (Reisman Decl. Ex. 7, Wang Dep. at 84:17-25.)
- 56. At the time Dr. Wang submitted his January 22, 2016 opinion letter in this case, he had not done a comprehensive literature search on occupational exposures and their ability to cause GPA and he had developed no opinion as to whether any substance causes GPA.

 (Reisman Decl. Ex. 7, Wang Dep. at 45:21-46:4, 162:2-9, 163:23-164:4.)
- 57. This is the first case in which Dr. Wang has reviewed the literature regarding the etiology of GPA. (Reisman Decl. Ex. 7, Wang Dep. at 82:22-83:2.)
- 58. Dr. Wang's knowledge on GPA was gained "via articles that were introduced to [him] some from Mr. Rizzo and some that, on my own review literature review." (Reisman Decl. Ex. 7, Wang Dep. at 93:2-10.)

- 59. Dr. Wang reviewed the literature regarding the cause of GPA in the weeks just prior to his deposition. (Reisman Decl. Ex. 7, Wang Dep. at 85:2-86:7, 93:15-94:6, 96:23-97:5, 108:6-10, 162:2-163:3.)
- 60. At his second deposition, Dr. Wang opined that GPA is causally associated with (1) nanosilica and (2) a solvent called trichloroethylene. (Reisman Decl. Ex. 7, Wang Dep. at 292:13-20, 301:7-303:24.)
- 61. Dr. Wang is not aware of any literature, study, text or article stating or reaching either of the causation conclusions he offered in this case. (Reisman Decl. Ex. 7, Wang Dep. at 300:2-6, 295:6-11, 188:14-189:4, 253:2-11, 300:12-16.)
- 62. No epidemiological study has even considered the relationship between nanosilica and GPA or trichloroethylene and GPA. (Reisman Decl. Ex. 7, Wang Dep. at 295:6-11, 355:22-24, 431:7-11).

VII. THE ARTICLES DR. WANG RELIES UPON DO NOT SUPPORT CAUSATION

- 63. Dr. Wang relies on one article to support his opinion that exposure to nanosilica causes GPA: Napierska, D., 2010. The nanosilica hazard: another variable entity. Part. Fibre. Toxicol. 7, 39-37 ("Napierska 2010"). (Reisman Decl. Ex. 7, Wang Dep. at 262:17-263:2, 302:9-24.)
- 64. Napierska 2010 does not mention GPA or ANCA-associated vasculitis. (Garabrant Decl. ¶ 63; Reisman Decl. Ex. 7, Wang Dep. at 263:13-15.)
- 65. Napierska 2010 does not make any conclusion with respect to exposure to silica and GPA. (Garabrant Decl. ¶ 63; Reisman Decl. Ex. 7, Wang Dep. at 263:4-12.)
- 66. Napierska 2010 is not an epidemiological study. (Reisman Decl. Ex. 7, Wang Dep. at 185:7-9; *see also*. Garabrant Decl. ¶ 63.)

- 67. There is no epidemiological study that investigates exposure to nanosilica. (Reisman Decl. Ex. 7, Wang Dep. at 355:22-24.)
- 68. Dr. Wang relies on two articles to support his opinion that exposure to trichloroethylene causes GPA:
 - Cooper, G.S., 2009. Evidence of Autoimmune-Related Effects of
 Trichloroethylene Exposure from Studies in Mice and Humans. Environ.

 Health Perspectives 117(5), 696-702 ("Cooper 2009"); and
 - Miller, F.W., 2012. Epidemiology of environmental exposures and human autoimmune diseases: findings from a National Institute of Environmental Health Sciences Expert Panel Workshop. J. Autoimmun. 39, 259-271 ("Miller 2012").

(Reisman Decl. Ex. 7, Wang Dep. at 372:15-19.)

- 69. Cooper 2009 is not an epidemiological study. It discusses *in vitro* data data collected from experiments performed outside of a living organism that point to a possible mechanism for development of autoimmune response. (Reisman Decl. Ex. 7, Wang Dep. at 371:3-12.)
- 70. The *in vitro* data in Cooper 2009 does not point to the development of GPA, ANCA-associated vasculitis or any specific autoimmune disease. (Reisman Decl. Ex. 7, Wang Dep. at 370:19-371:15.)
- 71. Miller 2012's findings are limited to ANCA-associated vasculitis. (Garabrant Decl. ¶ 64; Reisman Decl. Ex. 7, Wang Dep. at 360:2-17.)

- 72. Miller 2012 does not make any findings or conclusions specific to GPA. (Hoffman Decl. ¶ 32c; Garabrant Decl. ¶ 64; Reisman Decl. Ex. 7, Wang Dep. at 331:24-332:3, 360:18-20.)
- 73. Miller 2012 specifically noted that it did not have the evidence to draw a causal association with a specific disease subgroup such as GPA. (Reisman Decl. Ex. 7, Wang Dep. at 361:5-11.)
- 74. With respect to its evaluation of the potential association between solvents and ANCA-associated vasculitis, Miller 2012 was "not confident" about the association. (Reisman Decl. Ex. 7, Wang Dep. at 372:20-23.)
- 75. With respect to its evaluation of the potential association between solvents and ANCA-associated vasculitis, Miller 2012 did not note an association to be likely. (Reisman Decl. Ex. 7, Wang Dep. at 372:24-373:4; *see also* Garabrant Decl. ¶ 64.)

Dated: December 21, 2016 Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing was served by electronic transmission through the Court's Case Management Electronic Case Filing system to all counsel of record, this 21st day of December 2016.

/s/ Sharyl A. Reisman
Sharyl A. Reisman